



Graminex G63™ Flower Pollen Extract for Benign Prostatic Hyperplasia in Men





WHITE PAPER

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August 2014
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Graminex G63™ Flower Pollen Extract

for Benign Prostatic Hyperplasia in Men



Benign Prostatic Hyperplasia:

Benign prostatic hyperplasia (BPH) is a condition that directly affects the male prostate gland in aging men. As men age symptoms of BPH typically worsen. BPH is characterized by hyperplasia, or the abnormal proliferation of cells within the prostatic stromal area and prostate epithelial cells, which causes large nodules to form inside the prostate gland. The resulting inflammation in the prostate gland around the urethral canal causing obstruction symptoms to occur in the lower urinary tract system. Symptoms of BPH include abnormal urinary frequency, urinary urgency, urinary incontinence, nocturia (voiding at night), weak urinary stream, stream hesitancy, stream intermittency, straining to void and a sensation of incomplete voiding. (1) These symptoms are directly related to a man's quality of life. If not treated, over time BPH can block or squeeze the urethral canal completely closed, which leads to other urinary tract problems that overtime may damage the bladder and kidneys.

It is estimated that 50% of men show symptoms of BPH by the age of 50 years, and this increases to 75% in men over 80 years of age. (2) In 40-50% of these patients, the symptoms become clinically significant and require treatment. Symptoms of BPH may even begin to appear in men younger than 30 years of age. Treatment for BPH ranges from careful monitoring to invasive surgery. Mild cases of BPH are often times monitored without prescription drug treatment and patients are recommended to watchfully wait. Today there is a broad range of pharmaceuticals available to help treat the symptoms associated with BPH, however many patients are not willing to live with the side-effects of these drugs. More severe cases may now be treated with both invasive surgery and non-invasively with various laser treatments, many of which may or may not be successful. (3)

Despite new advances in treatment, men with mild to moderate BPH cases may still be told to watch and wait until the condition worsens before beginning a prescription drug treatment or undergoing a surgical procedure. Waiting for a condition to get worse before starting a treatment or therapy does not improve a patient's quality of life. This is where a dietary supplement product becomes useful to help improve the bothersome symptoms of BPH and to help improve not only a man's overall quality of life, but also their loved ones'.

Alternative Medicine:

Flower Pollen Extract is a standardized extract from flower

pollen that has been used historically for over 50 years to support prostate health. This product is supported by a substantial amount of open, placebo-controlled and double-blind clinical trials. Flower Pollen Extract has been given to men for prostate health with peace of mind and without harmful side effects as an alternative to pharmaceuticals for many BPH patients. (4)

Flower Pollen Extract is produced using a combination of unique growing and processing techniques. The raw pollen grains are harvested mechanically from the fields and are further processed to remove any plant material to isolate the pure pollen. Once in pure form, the pollen is extracted to remove the outer shell so the internal nutrients can be released. This extraction process is being done without the use of solvents by Graminex® in the Untied States. During the extraction process the outer shells of the pollen grains along with the allergens are discarded, leaving only the internal nutrients behind. Throughout this process substances that are toxic or harmful, like allergens and other high-molecular substances, are broken down and eliminated. The final product contains a synergistic formula of the natural and complete nutrition factors that are necessary to generate new life. This unique extract has been shown to help alleviate BPH and lower urinary tract symptoms in men.



G63™ Flower Pollen Extract Facts:

- Non-solvent extracted
- 100% manufactured in USA
- Standardized full spectrum formula
- Clinically supported for safety and efficacy
- cGMP, Kosher, Pareve, Halal and
- Organic Processing Certified

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Chemical Composition of Flower Pollen Extract:

The pollen grains used to manufacture G63™ Flower Pollen Extract contain a complete profile of nutrients vital for human health. Included in the chemical composition are a variety of vitamins, carotenoids, minerals, amino acids, enzymes, lipids, fatty acids, prostaglandins, phytosterols, hydrocarbons and flavonoids. These substances are all present naturally in the extract and have been shown to selectively act on the prostate cells to help alleviate BPH symptoms and improve prostate health. (5) G63™ Flower Pollen Extract is a standardized product that meets the exact specifications for phytosterol and amino acid content for every batch. It is manufactured using a combination of the water soluble, G60™ Flower Pollen Extract, and the lipid soluble, GFX™ Flower Pollen Extract, portions of the pollen grain. G60™ contains a standardized portion of amino acids and GFX™ contains a standardized portion of phytosterols. These two ingredients are blended into a 20:1 ratio to create a standardized, pharmaceutical grade powder. The unique chemical composition of the G63™ Flower Pollen Extract formula has been extensively studied for both safety and efficacy in the published literature. In addition to this G63™ Flower Pollen Extract has undergone complete toxicology studies.

Modes of Action: Anti-Inflammatory & Anti-Congestive

Inflammation of the prostate results in edema, or the abnormal accumulation of fluid in the interstitial stromal tissue surrounding the acini and ducts of the gland, leading to congestion and poor secretory drainage. The swelling of the prostate gland that occurs as a result of this process can affect the normal and the hyperplastic gland, causing difficulties with voiding, dysuria, frequency and nocturia. This swelling accounts for the discomfort and pain that occurs as a result of chronic non-bacterial prostatitis and prostatodynia. The anti-congestive action of Flower Pollen Extract is based on the inhibition of the prostaglandin and leukotriene biosynthesis during the arachidonic acid cascade (Figure 1).

The majority of known mediators that cause inflammation come from the membrane-bound arachidonic acid (6). The biosynthesis of these inflammatory mediators is initiated by two enzymes: cyclo-oxygenase and 5-lipoxygenase. The activities of both the cyclo-oxygenase and 5-lipoxygenase enzymes are markedly reduced as well as the overall quantity of arachidonic acid with Flower Pollen Extract treatment (Figure 2). The inhibition of the arachidonic acid cascade by

Flower Pollen Extract helps prevent intraprostatic tissue edema from occurring in the prostate's middle lobe as well as fibrosis. A secondary mechanism of action on the prostate gland serves to protect the acinar epithelial function and cell shape from nonbacterial inflammation. (7) These two mechanisms of action are able to have long term decongestive effects that lead to a lasting improvement of voiding difficulties and the residual urine decreases significantly. (8)

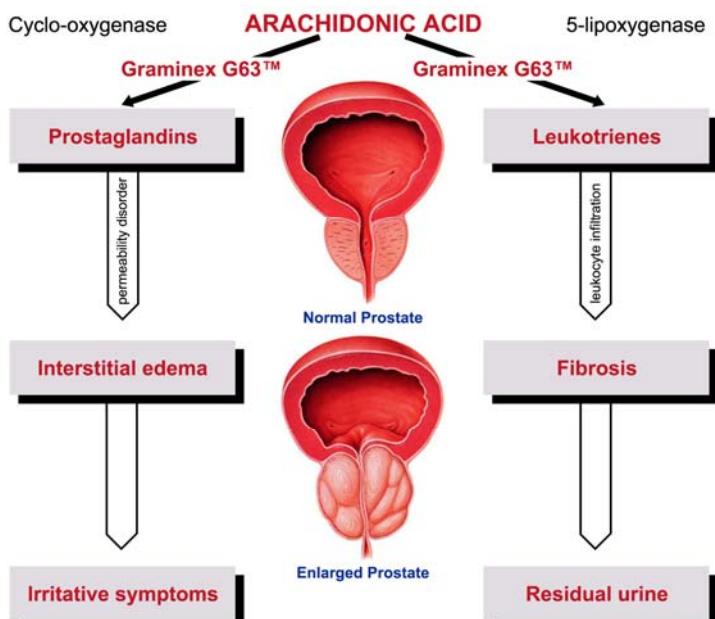


Figure 1: Graminex G63™ Flower Pollen Extract inhibits the cyclo-oxygenase and the 5-lipoxygenase, reducing biosynthesis of prostaglandins and leukotrienes.

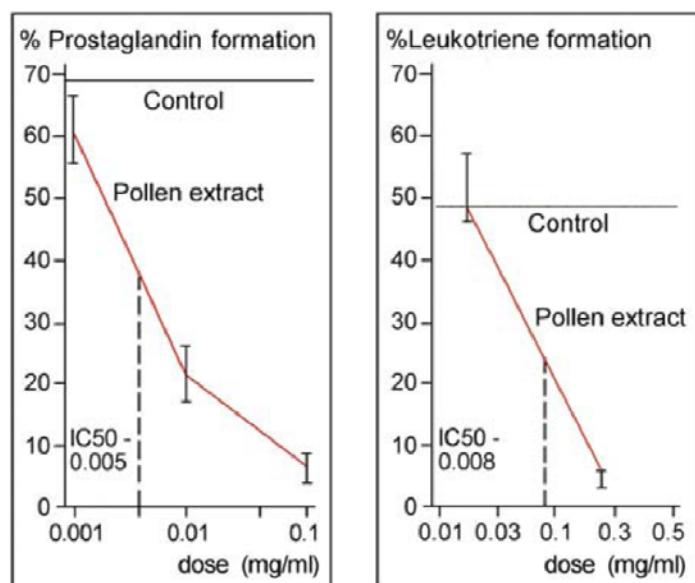


Figure 2: Marked reduction in the biosynthesis of prostaglandins and leukotrienes after treatment with Flower Pollen Extract (6).

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Efficacy Studies:

In stage II and stage III BPH patients, studies show the anti-inflammatory effect of Flower Pollen Extract is capable of leading to a marked reduction in prostate volume (9, 10). A transrectal ultra sonogram of the prostate, before and after six months of treatment with Flower Pollen Extract, clearly shows the marked reduction of the circumference, transverse and a-p diameter of the prostate (Figure 3). By reducing the internal swelling and fibrosis of the prostate, there is a significant reduction in the clinical symptoms associated with BPH.

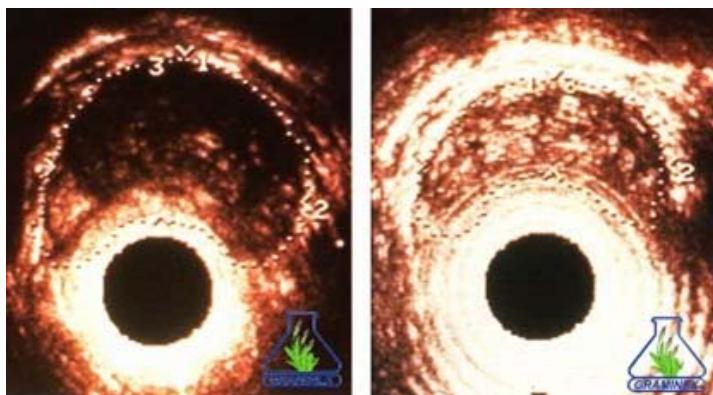


Figure 3: Transrectal ultra sonography of the prostate before and after six months treatment with Flower Pollen Extract. (11)

In BPH patients the anti-congestive effect of Flower Pollen Extract results in a lasting improvement of urinary voiding difficulties. High improvement rates are also obtained in nocturia, one of the main symptoms of BPH. After treatment, residual urine volume also has been shown to significantly decrease by an average of 47% (12). In a double blind, placebo controlled study, after administration of Flower Pollen Extract from Graminex®, a significant improvement in BPH patients was observed (Table 1). In another study conducted using G63™ Flower Pollen Extract, patients experienced an improving trend in their symptoms of perineal pain, erection difficulty, ejaculation difficulty and pain during urination throughout the course of treatment (4). Similar methods from other studies have also shown an improvement in chronic prostatitis and prostatodynia (13, 14). One study conducted with prostatodynia patients using Flower Pollen Extract™ demonstrated a marked improvement of the associated symptoms that are also common to BPH (15). On average the study showed 78% of patients showed an improvement in symptoms and 60% showed a complete cure (Table 2).

In the majority of patients there was either complete or lasting relief of symptoms. Numerous open label, placebo-controlled and double blind studies with Flower Pollen Extract provide an overwhelming amount of evidence that it is an effective product in helping reduce nocturia, daytime frequency and a sensation of residual urine (12, 16, 17, 18).

Parameter	Active Drug	Placebo	Significance P value
Clinical symptoms			
	Response (%)		
Nocturia	66.7	37.2	0.011
Frequency	6.9	37.0	0.023
Symptom-free (%)			
Frequency	45.2	15.2	0.003
Sensation of incomplete emptying	38.2	3.8	0.005
Urodynamics			
Residual urine	Volume		
-- before therapy (ml: $x \pm s$)	54.5 \pm 24.9	51.9 \pm 32.0	
-- after therapy (ml: $x \pm s$)	28.9 \pm 19.7	44.9 \pm 28.6	0.001
-- reduction (%)	47.0	13.5	

Table 1: Results of a double-blind study: Significant differences in favor of G63™ Flower Pollen Extract in clinical symptomatology and urodynamics (12).

Symptom	Symptom-free	Improved
Pain	52.4 %	76.2 %
Dysuria	60.0 %	76.7 %
Nocturia	57.1 %	92.9 %
Frequency	63.3 %	63.3 %
Discomfort	61.5 %	80.8 %

Table 2: Marked improvement of the symptoms in prostatodynia due to Flower Pollen Extract (15).

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After reviewing placebo-controlled trials, active controlled and open-label studies, Flower Pollen Extract may be considered a safe and effective therapy for the management of mild to moderate lower urinary tract symptoms caused by BPH and other prostate related conditions (19, 20).

G63™ Flower Pollen Extract Dosage

	G63™	G60™	GFX™
Pharmaceutical level dose	1500 mg/day	360 mg/day	18 mg/day
Average scientifically supported dose	1000 mg/day	240 mg/day	12 mg/day
Minimum scientifically supported dose	500 mg/day	120 mg/day	6 mg/day

Flower Pollen Extract is supported by over 100 clinical studies for various applications. These studies demonstrate the effectiveness of the product at varying dosages. Primary research as a pharmaceutical treatment has been conducted using a dose of 1500 mg/day. Independent clinics conducted have used a range of 500-1500 mg/day.

Conclusion

Flower Pollen Extract is an interesting ingredient in the nutraceutical and pharmaceutical industry for the treatment of BPH symptoms. As a natural botanical extract, G63™ Flower Pollen Extract may be used in combination with other dietary supplements and pharmaceuticals to help provide relief for men experiencing bothersome BPH symptoms. The unique growing, manufacturing process and exact standardization methods provide an extract that goes beyond and is superior to the normal botanical extracts and bee pollen on the market. The percentages of actives in each batch of G63™ Flower Pollen Extract are the same each and every time it is manufactured. In addition to the quality standards, there exists a substantial amount of clinical trial data to support Flower Pollen Extract's use for men's prostate health, specifically to reduce symptoms associated with BPH. Primary and secondary scientific literature provides sufficient evidence that Flower Pollen Extract is safe and effective for helping reduce the symptoms of BPH. Graminex has also conducted acute oral and acute dermal toxicity studies in addition to the LD50, to show that it is nontoxic and consider safe. The addition of G63™ Flower Pollen Extract to a quality product formulated for men's health will prove effec-

tive for both the manufacturers and end users.

G63™ Flower Pollen Extract is available as a bulk powdered ingredient as well as in a variety of private labeled products.



**Contact Graminex LLC to learn more about
G63™ Flower Pollen Extract
for Men's Health Applications**

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